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|---------------------------|-------------|----------------------|---------------------|------------------|
| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/561,973 | 12/22/2005 | Kazuyuki Ohmoto | Q92245 | 1551 |
| 65565 | 7590 | 11/23/2009 | EXAMINER | |
| SUGHRUE-265550 | | | DESAI, RITA J | |
| 2100 PENNSYLVANIA AVE. NW | | | ART UNIT | |
| WASHINGTON, DC 20037-3213 | | | PAPER NUMBER | |
| | | | 1625 | |
| | | | NOTIFICATION DATE | DELIVERY MODE |
| | | | 11/23/2009 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

SUGHRUE265550@SUGHRUE.COM
USPTO@SUGHRUE.COM
PPROCESSING@SUGHRUE.COM

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/561,973 | Applicant(s) OHMOTO ET AL. | |
| | Examiner Rita J. Desai | Art Unit 1625 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 and 23-25 is/are pending in the application.
- 4a) Of the above claim(s) 1-13 and 19-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-18 and 23-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/19/09, 8/28/09</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1-21, 23-25 are pending.

Claims 23-25, 14-18 are under examination and stand rejected.

Elected group is Va. As given by,

V(a), claims 23-25, 14-18 drawn to compounds and composition wherein A3 is a benzene, pyridine, pyrazine or a pyrimidine and R6 and R7 do not form a ring and R2, R3, R6 and R7 are each independently C1-8 alkyl, C2-8 alkenyl, C2-8 alkynyl, a hydroxyl, C1-8 alkoxy, mercapto, C1-8 alkylthio, amino, NR104R105, carboxyl, C1-6 alkoxy carbonyl, nitro, cyano, a halogen atom, oxo, acyl, formyl or tri(C1-6alkyl)silyl. (formula I-3-2 and not I-3-4 which requires both R4R5 and R6R7 to form a ring.)

The withdrawn claims have not been cancelled.

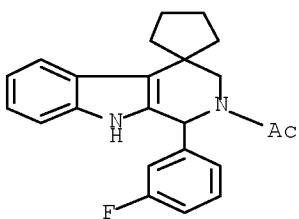
The rejection under 35 USC 112 still stands. Applicants amended does not overcome the rejection. The arguments that applicants have made 75 working examples is not convincing.

Applicants claims are drawn to compounds with numerous hetero cyclic and large substituents at various places and off of substituents.

The compounds made by the applicants which fall within the elected group are given below.

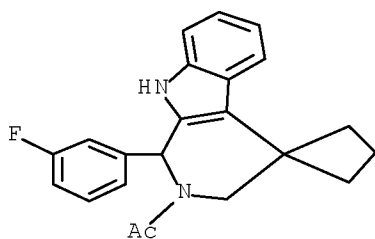
CN Ethanone, 1-[1'-(3-fluorophenyl)-1',2',3',9'-
tetrahydrospiro[cyclopentane-
1,4'-[4H]pyrido[3,4-b]indol]-2'-yl]- CN Spiro[cyclopentane-1,4'-
[4H]pyrido[3,4-b]indole],
2'-acetyl-1'-(3-fluorophenyl)-1',2',3',9'-tetrahydro- (9CI)

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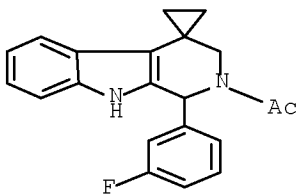


CN Ethanone, 1-[1'-(3-fluorophenyl)-1',2',3',9'-
tetrahydrospiro[cyclobutane-

1,4'-[4H]pyrido[3,4-b]indol]-2'-yl]-
CN Spiro[cyclobutane-1,4'-[4H]pyrido[3,4-b]indole],
2'-acetyl-1'-(3-fluorophenyl)-1',2',3',9'-tetrahydro- (9CI)

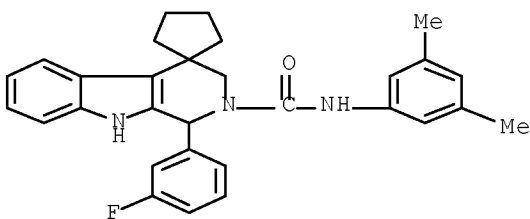


CN Spiro[cyclopropane-1,4'-[4H]pyrido[3,4-b]indole],
2'-acetyl-1'-(3-fluorophenyl)-1',2',3',9'-tetrahydro- (9CI)

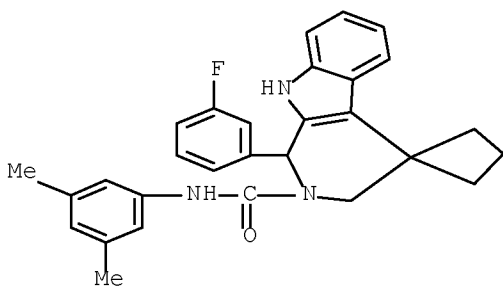


CN Spiro[cyclopentane-1,4'-[4H]pyrido[3,4-b]indole]-2' (3'H)-carboxamide,
N-(3,5-dimethylphenyl)-1'-(3-fluorophenyl)-1',9'-dihydro-

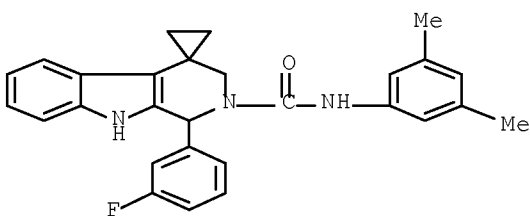
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CN Spiro[cyclobutane-1,4'-[4H]pyrido[3,4-b]indole]-2' (3'H)-carboxamide,
N-(3,5-dimethylphenyl)-1'-(3-fluorophenyl)-1',9'-dihydro-



CN Spiro[cyclopropane-1,4'-[4H]pyrido[3,4-b]indole]-2' (3'H)-carboxamide,
N-(3,5-dimethylphenyl)-1'-(3-fluorophenyl)-1',9'-dihydro-



These compounds have a very limited scope of substituents.

As these compounds do not have any other art, it would be unpredictable and would require an undue amount of experimentation.

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The instantly claimed compounds are not structurally similar to known compounds having the same activity and their pharmacological properties can not be predicted from their chemical structure, thus a disclosure that they possess a particular activity is not enough.

As a result necessitating one of ordinary skill to perform an exhaustive search for which compounds of the claims can treat disorders and if sufficient starting materials are available to make them.

Applicants specifications are devoid of the starting materials to make compounds with the various substituents. For e.g. A4 being substituted with a het ring,

R4 and R5 together forming a cycloalkyl ring and then further being substituted

R⁴ and R⁵ are together with their binding carbon atom to form C3-8 cycloalkyl which may be substituted with 1 to 4 substituent(s) optionally selected from C1-8 alkyl, C2-8 alkenyl, C2-8 alkynyl, a carbocyclic ring, a heterocyclic ring, hydroxyl, C1-8 alkoxy, amino, NR¹⁰⁴R¹⁰⁵, carboxyl, C1-6 alkoxy carbonyl, nitro, cyano, a halogen atom, oxo, acyl, formyl and tri(C1-6 alkyl)silyl;

And then again the B benzene being further substituted a carbocyclic ring or a hetero ring.

These substituents with the numerous combinations and subcombinations is a very complex issue and making and using these compounds is very unpredictable especially in view of the fact that there are none in the prior art.

Thus the rejection has been maintained.

The Double patenting rejection over application 11/722623 is also maintained as applicants have not provided a TD as yet.

Clarification regarding claim 25 : Claim 25 is also rejected.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, flex time..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Rita J. Desai/
Primary Examiner, Art Unit 1625

November, 9th 2009.